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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,761	09/11/2003	Alan John Kingsman	674523-2005.2	9467

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EXAMINER	
SCHNIZER, RICHARD A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 06/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/661,761	KINGSMAN ET AL.	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *63-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *63-74 and 77-81* is/are rejected.

7)☒ Claim(s) *75 and 76* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09224014.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 63-81 are pending and under consideration.

Finality of the previous action is withdrawn in view of the following new grounds of rejection not necessitated by amendment.

Rejections Withdrawn

The obviousness rejections citing Verma (US Patent 6013516) and Chang (1995) are withdrawn. After further consideration, and as discussed in the interview with Anne-Marie Yvon and Jill Martin on 5/16/06, this combination of references does not render obvious the claimed invention because there is insufficient motivation to combine them. At the time of the invention Tat protein was not thought to be part of a viral particle. So although Tat was implicated in Kaposi's sarcoma, there would be no motivation to delete tat nucleic acids from the nucleic acids used to produce a retroviral particle because Tat would not be expected to be included in the particle. Also Tat would not be expressed by the vector genome because this genome does not encode Tat.

No double patenting rejections are made over the instant claims because Applicant filed a terminal disclaimer over US Patents 6,312,682 and 6,669,936 on 12/9/05.

The rejection of claims 63-81 for lack of adequate written description is overcome by Applicant's amendment.

Claim Rej ctions - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 63-65, 68-74, and 77-81 are rejected under 35 U.S.C. 102(b) as being anticipated by Luznik (J. Clin. Invest. 95: 328-332, 1995).

Luznik taught a lentivirus based retroviral vector production system that can produce an HIV vector that is replication deficient in U937 cells. The system comprises *tat*- proviral DNA clones. Replication can be induced in these cells by addition of phorbol esters. See abstract, page 329, column 1, last full paragraph, and Fig. 1C. Viruses produced from one proviral cDNA clone (HIV-$1_{NL\ 4.3\ (tat-)}$) infected Molt 4/8 cells. See paragraph bridging pages 329 and 330.

Regarding claim 73 which requires three DNA constructs encoding (i) the genome of the vector, (ii) gag and pol, and (iii) env, Luznik taught a DNA vector comprising the vector genome and gag, pol, and env genes (see e.g. Fig. 2 on page 160). Each portion of the vector corresponding to items (i-iii) above can be considered to be a "construct", wherein the genome construct comprises constructs 'ii' and 'iii'. Genes encoding gag, pol, and env are considered to be nucleotide sequences of interest.

Thus Luznik anticipates the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 63-74, and 77-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luznik (J. Clin. Invest. 95: 328-332, 1995) view of either one of Bray et al (Proc. Nat. Acad. Sci. USA 91: 1256-1260, 1994) or Hammarskjold et al (US Patent 5585263).

Luznik taught a lentivirus based retroviral vector production system that can produce an HIV vector that is replication deficient in U937 cells. The system comprises *tat*- proviral DNA clones. Replication can be induced in these cells by addition of phorbol esters. See abstract, page 329, column 1, last full paragraph, and Fig. 1C. Viruses produced from one proviral cDNA clone (HIV-$1_{NL\ 4.3\ (tat-)}$) infected Molt 4/8 cells. See paragraph bridging pages 329 and 330. Thus Luznik anticipates and renders obvious claims 63-65, 68-74, and 77-81.

Luznik does not teach a constitutive transport element required by claims 66 and 67.

Bray et al taught that a 219 base fragment of Mason Pfizer monkey virus was capable of substituting for Rev and the RRE in promoting transport of intron-containing

HIV mRNA. See entire document, especially page 1256, column 2 last full paragraph before MATERIALS AND METHODS.

Hammarskjold disclosed the same 219 base fragment of Mason Pfizer monkey virus and taught that it was functionally equivalent to the HIV RRE. See entire document, especially column 6, lines 8-13.

It would have been obvious to one of ordinary skill in the art at t he time of the invention to substitute the Mason Pfizer monkey virus CTE for the RRE of Luznik. MPEP 2144.06 indicates that when it is recognized in the art that elements of an invention can be substituted, one for the other, while retaining essential function, such elements are art-recognized equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. In re Fout, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). Furthermore, MPEP 2144.07 indicates that the selection of a known material based on its suitability for its intended use supports the determination of prima facie obviousness. See also Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945).

Thus the invention as a whole was prima facie obvious.

Conclusion

No claim is allowed. Claims 75 and 76 are objected to because they depend from rejected claims, but would be allowable if rewritten in independent form incorporating all of the limitations of the claims from which they depend.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Peter Paras, can be reached at (571) 272-4517. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Richard Schnizer, Ph.D.
Primary Examiner
Art Unit 1635